## 510(k) Summary of Safety and Effectiveness for the Trident™ All Poly Cup

DEC 11 2000

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| Proprietary Name: | Trident™ All Poly Cup |
| Common Name: | All Polyethylene Acetabular Cup |
| Classification Name and Reference | 21 CFR §888.3350, Hip joint metal/polymer semi-constrained cemented prosthesis |
| Device Product Code: | JDI, prosthesis, hip, semi-constrained, metal/polymer, cemented |
| For Information Contact: | Karen Ariemma<br>Howmedica Osteonics Corp.<br>59 Route 17<br>Allendale, NJ 07401-1677<br>Phone: 201-760-8187<br>Fax: 201-760-8435 |

The Trident™ All Poly Cup is a polyethylene acetabular component that is intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This cup is designed to be cemented into the acetabulum.

The Trident™ All Poly Cup is available in standard UHMWPE in outer diameters of 40mm to 66mm in two millimeter increments through 60mm and 3mm increments through 66 (where applicable), and inner diameters of 22mm, 26mm, 28mm, and 32mm. The Trident™ All Poly Cup is available in Crossfire UHMWPE in a 22 mm inner diameter with outer diameters of 42 mm to 60mm in two millimeter increments, a 26 mm inner diameter with outer diameters of 46-66 mm in two millimeter increments through 60mm and 3mm increments through 66, a 28 mm inner diameter with outer diameters of 48-66 mm in two millimeter increments through 60mm and 3mm increments through 66 and a 32 mm inner diameter with outer diameters of 52-66 mm in two millimeter increments through 60mm and 3mm increments through 66. These cups are manufactured from Ultra High Molecular Weight Polyethylene which conforms to ASTM F-648.

The substantial equivalence of the Trident™ All Poly Cup is based on an equivalence in materials, design and intended use to Howmedica Osteonics' Premise® Hip Acetabular Component, Howmedica Osteonics' Contemporary Acetabular Component and Biomet's Ranawat/Burstein Cemented Acetabular Cup.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K001956
Trade Name: Trident™ All Poly Cup
Product Code: JDI
Regulatory Class: II
Dated: September 18, 2000
Received: September 19, 2000

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 001956

Device Name: Trident™ All Poly Cup

Indications For Use:

The Trident™ All Poly Cup is a polyethylene acetabular component that is intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This cup is designed to be cemented into the acetabulum. These acetabular cups are intended to be used with any Howmedica Osteonics' femoral head.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K001956